PSJ10 Exh 57

From: Nathalie Leitch
To: Jennifer Altier
Sent: 7/22/2011 11:40:52 AM
Subject: FW: Oxymorphone training to KADIAN sales team
Attachments: image001.gif; Oxymorphone Sales Training v2 A347.pptx

fyi

Nathalie Leitch
Director, Specialty Rx Products

Actavis
60 Columbia Rd. Bldg B t +1 973-889-6968 @ NLeitch@actavis.com
Morristown , NJ 07960 United States w www.actavis.com <http://www.actavis.com/>
Internal VoIP number t 125 6968

From: David Myers
Sent: Friday, July 22, 2011 12:40 PM
To: Ara Aprahamian RPh
Cc: Jinping McCormick; Nathalie Leitch
Subject: Oxymorphone training to KADIAN sales team
Importance: High

Hi Ara,

The attached slide deck is approved for use in Monday's presentation to the KADIAN sales team. Please give me a call at the number listed below if you have any questions. (You can also reach me on my mobile at 410-591-5743.)

Thanks,

David

David Myers
Senior Manager, Products & Communications

Actavis
60 Columbia Rd. Bldg B t +1 973-993-4503 @ DMYERS@actavis.com
Morristown , NJ 07960 United States f 973-993-4302 w www.actavis.com <http://www.actavis.com/>

Internal VoIP number t 1254503


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Introduction of
Oxymorphone Hydrochloride Extended-Release Tablets, CII

Sales Training Class

A347 Rev 7/2011

The Latest News from Actavis

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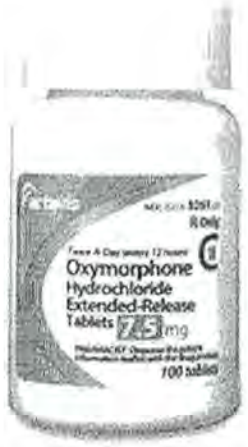
Actavis launches generic Oxymorphone Hydrochloride Extended-Release Tablets, CII 7.5mg and 15mg (AB-rated to Opana ER®*) in July

...and we'd like your help to increase awareness regarding the availability of this new product!



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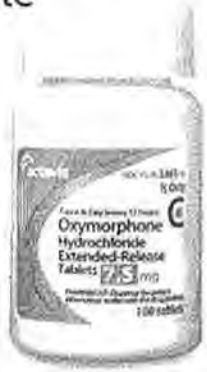
Oxymorphone Overview

- Oxymorphone Hydrochloride Extended-Release Tablets, CII is available from Actavis in 7.5mg and 15mg, bottles of 100's.
- AB-rated to Opana ER®* by Endo Labs.
- Opana ER was originally available in 7 strengths: 5mg, 7.5mg, 10mg, 15mg, 20mg, 30mg and 40mg.
- Endo discontinued the 7.5mg and 15mg strengths in March, 2011. *Normally, it is not necessary to promote a generic product to physicians, but since the brand discontinued these strengths, we have to increase awareness of their availability at the prescribing level. (Endo did not withdraw these strengths due to safety reasons.)*
- We believe that Actavis is the first, and perhaps only, generic available in the 7.5mg and 15mg strengths at initial launch.
- Product launched on July 15th, shipped to all major wholesalers.

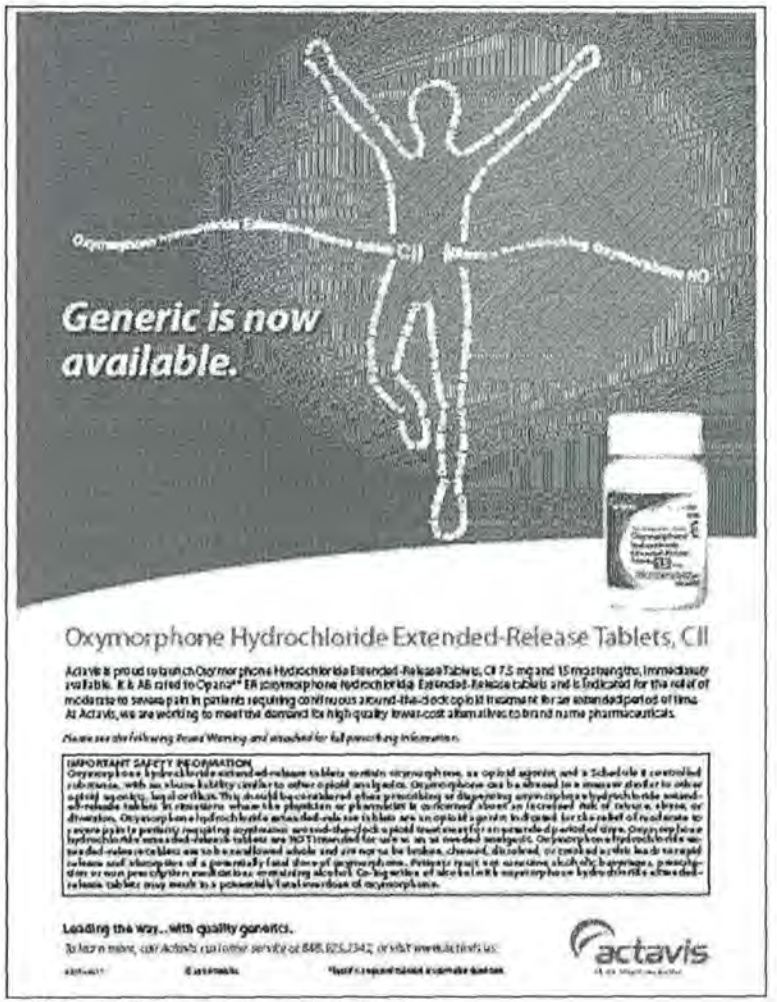


Key Messages

Example script to use when introducing Actavis' generic Oxymorphone:

- "Doctor, you may know that two strengths of Opana ER®* , 7.5mg and 15mg, were withdrawn earlier this year by Endo. This action was a business decision and these strengths were not withdrawn due to safety reasons. I would like to make you aware that generic versions of these strengths, which are AB-rated to the brand, are now available from Actavis. Please consider prescribing these generic strengths for the appropriate patients."
- Generic product is stocked at all major wholesalers and readily available.

Sell Sheet - front & back



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Marketing Support

- A two wave **direct-mail campaign** to the top 10,000 prescribing doctors. The first wave is planned to coincide with our launch to bring awareness to prescribing doctors. A follow-up mailing is planned for four weeks post-launch.
- **Journal advertising** to cover both prescribers and pharmacists:
  - Practical Pain Management - focused on pain specialists. Circulation: 45,000. Insertion in August 2011 issue.
  - Pharmacy Times - focused on Pharmacists/Pharmacy buyers. Circulation: 163,500. Insertion in August 2011 issue.
- **Email campaign** reaching a pharmacy audience of 87,000 addresses.
- Engaging major chains and wholesalers with targeted marketing programs aiming at pharmacist, doctors and patients

Indications and Usage

- Oxymorphone hydrochloride extended-release tablets are indicated for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.

Limitations of Usage

- Oxymorphone hydrochloride extended-release tablets are not intended for use as an as needed analgesic.
- Oxymorphone hydrochloride extended-release tablets are not indicated for pain in the immediate post-operative period if the pain is mild, or not expected to persist for an extended period of time.
- Oxymorphone hydrochloride extended-release tablets are only indicated for post-operative use if the patient is already receiving the drug prior to surgery or if the post-operative pain is expected to be moderate or severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate. (See American Pain Society guidelines).

Oxymorphone Boxed Warning

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WARNING: POTENTIAL FOR ABUSE, IMPORTANCE OF PROPER PATIENT SELECTION AND LIMITATIONS OF USE

Potential for Abuse

Oxymorphone hydrochloride extended-release tablets contain oxymorphone, which is a morphine-like opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics.

Oxymorphone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing oxymorphone hydrochloride extended-release tablets in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

Proper Patient Selection

Oxymorphone hydrochloride extended-release tablets are an extended-release oral formulation of oxymorphone indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

Limitations of Use

Oxymorphone hydrochloride extended-release tablets are NOT intended for use as an as needed analgesic.

Oxymorphone hydrochloride extended-release tablets are to be swallowed whole and are not to be broken, chewed, dissolved, or crushed. Taking broken, chewed, dissolved, or crushed oxymorphone hydrochloride extended-release tablets leads to rapid release and absorption of a potentially fatal dose of oxymorphone.

Patients must not consume alcoholic beverages, or prescription or non-prescription medications containing alcohol, while on oxymorphone hydrochloride extended-release tablet therapy. The co-ingestion of alcohol with oxymorphone hydrochloride extended-release tablets may result in increased plasma levels and a potentially fatal overdose of oxymorphone.

Important Safety Information

IMPORTANT SAFETY INFORMATION

Oxymorphone hydrochloride extended-release tablets contain oxymorphone, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. Oxymorphone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing oxymorphone hydrochloride extended-release tablets in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion. Oxymorphone hydrochloride extended-release tablets are an opioid agonist indicated for the relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time. Oxymorphone hydrochloride extended-release tablets are NOT intended for use as an as needed analgesic. Oxymorphone hydrochloride extended-release tablets are to be swallowed whole and are not to be broken, chewed, dissolved, or crushed as this leads to rapid release and absorption of a potentially fatal dose of oxymorphone. Patients must not consume alcoholic beverages, prescription or non prescription medications containing alcohol. Co-ingestion of alcohol with oxymorphone hydrochloride extended-release tablets may result in a potentially fatal overdose of oxymorphone.

Contraindications

- Oxymorphone hydrochloride extended-release tablets are contraindicated in patients with known hypersensitivity to oxymorphone or any of the tablet components, or with known hypersensitivity to morphine analogs such as codeine. This includes in patients with respiratory depression, and in patients with acute or severe bronchial asthma or hypercarbia.
- Oxymorphone hydrochloride extended-release tablets are contraindicated in any patient who has or is suspected of having paralytic ileus.
- Oxymorphone hydrochloride extended-release tablets are also contraindicated in patients who have moderate or severe hepatic impairment.
- The most serious adverse reactions associated with the use of oxymorphone hydrochloride extended-release tablets are respiratory depression, misuse and abuse, and CNS depressant effects.
- The most common adverse reactions are nausea, constipation, dizziness, somnolence, vomiting, pruitus, headache, sweating increased, and sedation.

- Please visit www.actavis.us/oxymorphone for Full Prescribing Information and other important Safety Information.

FAQs

- Q1: Is the generic product as effective as the brand?

  A1: This product is approved by FDA and AB rated to Opana ER®*.

- Q2: What does an AB rating mean?

  A2: AB rating means that FDA has determined that the generic product is pharmaceutically and therapeutically equivalent to the brand Opana ER®*.

- Q3: What about the other strengths?

  A3: Based on public information, the other strengths may become available in CY 2013.

FAQs – cont'd

- Q4: Where will this product be stocked? Can patients easily get their scripts filled?

  A4: This product is stocked at all major wholesalers and major drug chain stores. Patients should be able to get their scripts filled easily.

- Q5: Do I have to do anything special when writing a script?

  A5: Nothing different from what you normally do.

- Q6: Are you shifting your focus to marketing generics?

  A6: No, KADIAN® is still our focus product; we just want to make you aware that Actavis has a generic division that is marketing this product.

DOs

- Do discuss the generic product availability
- Do mention that generic product is AB rated to Opana ER®*
- Do mention that brand discontinued the 7.5mg and 15mg strengths
- Do mention that Endo did not withdraw these strengths for safety reasons
- Do leave the sell sheet with the prescribers (insert is attached)
- Do mention that this drug contains a boxed warning, so please refer to the complete safety information (as provided in the insert) when considering this drug for your patients

DON'Ts

- Do not provide information outside of the scope of this training
- Do not compare products
- Do not discuss or mention pricing
- We have provided product indication and safety information in this presentation for your information should questions arise. Always remember this is a boxed warning product and any discussion of the indication or benefits must include safety information. *In your interactions with physicians limit conversations regarding the indication of the product or defer to medical affairs as this is not intended to be a risk/benefit discussion. This is merely an availability announcement.*

Additional information

- For general medical questions and product information, please contact Medical Affairs:

  Call: 800-432-8534, Prompt #2

  Fax: 908-659-2685

  Email: medicalaffairs@actavis.com

- This is a different number from that used for Kadian

Compensation and Incentives

- **Team Award**
  - Top regional team with the highest cumulative Rx written for the period of August - October 2011
  - Each member of the team wins $500
- **Individual Award**
  - Top two performers from each team with the highest cumulative Rx written for the period of August - October 2011
  - Each individual award is $1000
- **Renewable upon review of overall performance**

Prescription Data

Average Monthly TRx				
Strength	Jan-Mar 2011 Average TRx	Apr 2011 TRx	May 2011 TRx	Jun 2011 TRx
15mg	5760	4188	2515	1595
7.5mg	1340	793	511	320
Total TRx	**7100**	**4981**	**3026**	**1915**

Additional Information

- Thank you for your assistance in promoting awareness of this newly-launched Actavis generic product! However, we'd like to confirm that informing prescribers of the availability of generic strengths of Oxymorphone should not detract from your time detailing KADIAN®. KADIAN® is still the primary focus of your sales call.

Thank you!